UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,805	12/02/2003	Harold H. Schmitz	1010-133US1	3329

32260 7590 08/09/2006

NADA JAIN, P.C.
560 White Plains Road, Suite 460
Tarrytown, NY 10591

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,805	SCHMITZ, HAROLD H.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/30/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8,13-28 and 33* is/are pending in the application.

4a) Of the above claim(s) *19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8, 13-18 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-8, 13-28 and 33 are pending in the application.

Election/Restrictions

This application contains claims 19-28 drawn to an invention nonelected with traverse in the response filed 12/16/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 5-8, 13-18 and 33 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8 and 13-18 remain rejected and new claim 33 is now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection remains standing for the reasons of record.

Applicant's arguments were fully considered, but not found convincing. Applicant argues that they have discovered a diagnostic tool that "allows for individualized diagnosis". that "...the specification defines 'baseline cytokine level' and teaches that a subject's 'baseline cytokine level' can be obtained by extracting a body sample, such as blood and measuring the level of cytokines in the sample'..". Applicant contends that "By comparing TGF-beta levels after incubation of each diagnostic sample with the baseline TGF-beta level....a subject can be diagnosed as a low or a high baseline TGF-beta producer" (page 7, Arguments).

Again, it has not been absolutely established, as keenly pointed out in the previous Office Action, that modulation of TGF-beta in the subjects tested in the Instant specification actually indicates that they are low or high baseline producers of TGF-beta, because there is no established 'correct' baseline for TGF-beta.

Applicant argues that "Once a subject is diagnosed as low or high...a person of skill in the art would know to identify which condition(s) the subject suffers from, or more importantly is at risk of, given known correlations between TGF-beta and certain medical conditions such as atherosclerosis.....Once diagnosed, dietary and

pharmaceutical regimens can be designed, and a subject may be treated..." (p. 8, Arguments).

However, again, because the cocoa composition of the Instant disclosure has some modulating effect on TGF-beta levels in the subjects described in the Instant specification, there is no evidence that the levels of these subjects would lead the skilled artisan to believe that there is any other underlying condition associated with their individual TGF-beta levels such as atherosclerosis and so-forth. Further, Applicant admits that 'dietary and pharmaceutical regimens can be designed'. Here, it is clear that Applicant has not designed any dietary or pharmaceutical regimens and therefore the claims lack Written description in the original disclosure as filed.

Claims 5-8 and 13-18 remain rejected and new claim 33 is now also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant states that 'The Examiner states that only claims directed to TGF-beta are enabled' (p. 8, Arguments). However, this is not what the Examiner stated in its entirety, what the Examiner stated is the following:

> It is noted that the claims are not enabled because there are no enabled embodiments in the claims. However, **there is an enabled embodiment found in the Specification, which is the modulation of TGF- β by use of cocoa derived catechin and epicatechin.**

However, the Examiner also noted that:

> Therefore, although the claims are not enabled in their entirety (and a rejection supporting lack of enablement follows), if Applicant chooses to amend the claims to reflect the enabled scope which is found in the Specification, the Examiner has also indicated scope of enablement problems below. (emphasis added).

Applicant argues that "Applicants need not enable all cells in the body of a human or veterinary animal because a person of skill in the art would know which cells express TGF-beta and thus would know how to select a suitable body sample to use in the methods of claims 1-19 and 29-32" (pp. 8-9, Arguments).

Again, the methods set forth in the Instant claims are deemed non-enabled and highly unpredictable. It is not clear that Applicant has discovered a nexus between the mechanism by which certain polyphenols in cocoa modulate TGF-beta and diagnosis of disease states. Thus, the skilled artisan would not have any reasonable expectation in practicing the invention absent any clear teachings in the Specification.

Applicant argues that "...specific diseases related to varying levels of TGF-beta as well as other cytokines were well known in the art as of the effective filing date of the application. For example, decreased levels of TGF-beta1 had been detected in subjects with advanced atherosclerosis...,excess TGF-beta1 has been shown to lead to cardiac fibrosis,...renal disease or failure, coronary heart disease...and coronary vasculopathy following cardiac transplantation..." (p. 9, Arguments). However, these values of TGF-beta are assessed based upon the patients 'typical' TGF-beta level as compared to a later value. Also, as indicated in the previous Office Action, a 'high' or 'low' level of TGF-beta does not necessarily mean that a person will in fact ever be diagnosed with any disease condition.

The response argues that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of *essentially limitless breadth* so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

Applicant essentially argues that one of skill in the art would 'know' how to treat a patient with a 'low' or 'high' baseline level of TGF-beta, however, the Instant specification does not clearly indicate that the measured value changes of TGF-beta as shown in subjects within the Instant specification is any indication that these subjects suffered from TGF-beta levels which were in any way abnormal. Further, the Instant specification teaches no means of diagnosing or treating any disease by the methods set forth in the Instant disclosure.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

August 1, 2006